510(k) Summary
Lucent®

510(k) Number K122967

FEB 2 1 2013

Manufacturer Identification

Submitted by:
Spinal Elements, Inc.
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760-607-0121

Contact Information:
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Date Prepared: November 9, 2012

Proprietary Name	Lucent®
Common Name	Intervertebral Body Fusion Device
Device Classification	21 CFR 888.3080 (Intervertebral Body Fusion Device)
Proposed Regulatory Class	Class II
Device Product Code	MAX

Purpose of this Special 510(k)
This Special 510(k) seeks clearance for a modification (larger sizes - line addition) to Lucent® intervertebral body fusion devices previously cleared under K071724, K073348, and K110632.

Device Description
This product is an intervertebral body fusion device for use in lumbar spinal surgery. It may also be referred to as an interbody device or interbody cage. The device is generally box-shaped with various holes throughout its design to allow for the placement of autograft. The exterior of the device has "teeth" or other generally sharp engagement members on the superior and inferior surfaces to help prevent the device from migrating once it is surgically positioned. The devices may be manufactured from titanium (Ti-6Al-4V) conforming to ASTM F 136 or ISO 5832-3, polyetheretherketone materials conforming to ASTM F 2026 or polyetheretherketone with a plasma sprayed coating of commercially pure titanium (per ASTM F 1580) on their superior and inferior surfaces.

Intended Use of the Device

Lucent® intervertebral body fusion devices are intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

This device is intended to be used with autogenous bone graft. Patients must have undergone a regimen of at least six (6) months non-operative treatment prior to being treated with this device.

Performance Data

The following testing was performed:
Static torsion, ASTM F 2077

Substantial Equivalence

The subject Lucent intervertebral body fusion device was shown to be substantially equivalent to previously cleared devices in indications for use, design, function, and materials used.

- Lucent 510(k) K071724, K073348 and K110632

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 21, 2013

Spinal Elements, Incorporated
% Mr. Benjamin A. Kimball
Regulatory Affairs Manager
2744 Loker Avenue West, Suite 100
Carlsbad, California 92010

Re: K122967
Trade/Device Name: Lucent®
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: September 24, 2012
Received: September 25, 2012

Dear Mr. Kimball:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) K:

Device Name: Lucent®

Indications for Use:
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Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Stephanie Bechtold -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K122967